



BRCAAnalysis CDx®
FDA Approved BRCA1 and BRCA2 Analysis Result

PHYSICIAN	SPECIMEN	PATIENT
	Specimen Type: Blood Draw Date: Jan 08, 2015 Accession Date: Jan 09, 2015 Report Date: Jan 20, 2016	Name: Patient, Test Date of Birth: Jan 01, 2000 Patient ID: Gender: Female Accession #: 01855323-BLD Requisition #: 4347335
Physician: Test Physician, MD		

Test Results and Interpretation

GENETIC VARIANT OF UNCERTAIN SIGNIFICANCE

<u>Test Performed</u>	<u>Result</u>	<u>Interpretation</u>
<i>BRCA1</i> sequencing comprehensive rearrangement	No Mutation Detected No Mutation Detected	No Mutation Detected No Mutation Detected
<i>BRCA2</i> sequencing comprehensive rearrangement	G1552V (4883G>T) No Mutation Detected	Uncertain Significance No Mutation Detected

The majority of deleterious or suspected deleterious variants identified by Myriad in *BRCA1* and *BRCA2* are classified using objective criteria based on the type and genomic position of the variants. Deleterious or suspected deleterious mutations classified by other criteria that are based on available evidence may be subject to change. If you have questions or concerns about how the variant(s) in this result report was classified, please contact Myriad.

Intended Use: BRCAAnalysis CDx® is an *in vitro* diagnostic device intended for the qualitative detection and classification of variants in the protein coding regions and intron/exon boundaries of the *BRCA1* and *BRCA2* genes using genomic DNA obtained from whole blood specimens collected in EDTA. Single nucleotide variants and small insertions and deletions (indels) are identified by polymerase chain reaction (PCR) and Sanger sequencing. Large deletions and duplications in *BRCA1* and *BRCA2* are detected using multiplex PCR. Results of the test are used as an aid in identifying ovarian cancer patients with deleterious or suspected deleterious germline *BRCA* variants, who are or may become eligible for treatment with Lynparza™ (olaparib). This assay is for professional use only and is to be performed only at Myriad Genetic Laboratories, a single laboratory site located at 320 Wakara Way, Salt Lake City, UT 84108.

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Please contact Myriad at 1-800-469-7423 with any questions or feedback regarding services provided.

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These test results should only be used in conjunction with the patient's clinical history and any previous analysis of appropriate family members. It is strongly recommended that these test results be communicated to the patient in a setting that includes appropriate counseling. Lynparza is a trademark of the AstraZeneca group of companies.



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The information below has not been reviewed and approved by the FDA.

This assay may identify ovarian cancer patients with a deleterious or suspected deleterious *BRCA1* or *BRCA2* mutation who may benefit from treatment with Lynparza™ (olaparib). Full prescription information for Lynparza™ (olaparib) is available at http://www.azpicentral.com/Lynparza/pi_lynparza.pdf. In addition, the assay may identify patients at risk for Hereditary Breast and Ovarian Cancer (HBOC) associated with *BRCA1* and *BRCA2* deleterious or suspected deleterious mutations.

The *BRCA2* variant G1552V results in the substitution of valine for glycine at amino acid position 1552 of the *BRCA2* protein. Variants of this type may or may not affect the function of the protein encoded by the gene in which it is found. Therefore, the contribution of this variant to the relative risk of breast, ovarian, pancreatic, or other cancers cannot be established from this analysis.